

# MutaCLEAN<sup>®</sup> Rapid extraction kit

*For rapid lysis of dry pharyngeal swab samples*

Valid from 2022-06-24

COMPONENT 1 NR1



COMPONENT 2 NR2



→REF KG1041



IVD



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## 1 INTENDED USE

The MutaCLEAN® Rapid kit is designed for nucleic acid release (RNA / DNA) from dry pharyngeal swabs. The kit can be used as an accessory in combination with a downstream in vitro diagnostic procedure and is intended to be used by professional users in a laboratory environment. It can be performed manually or using an automated platform.

## 2 MODE OF ACTION

The MutaCLEAN® Rapid Kit is a two-component lysis reagent system designed for the lysis of the SARS-CoV-2 coronaviruses and other enveloped respiratory viruses from dry pharyngeal swab specimens.

For sample preparation, the dry swabs are resuspended in a defined volume of the MutaCLEAN® Rapid lysis reagent. The MutaCLEAN® Rapid lysis reagent is a working solution consisting of Component 1 and Component 2. The RNA/DNA in the samples is released by an incubation time of ten minutes at room temperature in the MutaCLEAN® Rapid lysis reagent.

The MutaCLEAN® Rapid Kit is a fast and efficient method for the lysis of enveloped respiratory viruses, since no further steps are required for sample preparation apart from incubation of the samples in the MutaCLEAN® Rapid lysis reagent.

## 3 COMPONENTS

MutaCLEAN® Rapid Kit KG1041 is designed for 1000 isolations.

Table 1: Components of the MutaCLEAN® Rapid extraction kit.

Label	Content
NR1 Component 1	1 x 270 ml
NR2 Component 2	1 x 30 ml

## 4 EQUIPMENT AND REAGENTS TO BE SUPPLIED BY USER

Note: Consumables needed are dependent of the mode of sample preparation, e.g. manual lysis procedure or lysis using an automated system. Therefore, the customer needs to decide, which consumables are necessary for the extraction process.

- Laboratory equipment according to national safety instructions
- Vortex

- Nuclease-free, sterile sample tubes (1.5 or 2.0 mL microcentrifuge tubes)
- Sterile swab collection tube
- Pipets (adjustable volume)
- Sterile pipet tips with filter
- Tabletop microcentrifuge capable of 13,000 x g centrifugal force

## 5 TRANSPORT, STORAGE AND STABILITY

The MutaCLEAN® Rapid Kit components are shipped at ambient temperature. If the components are stored correctly are stable until the date of expiry printed on the label. Do not use reagents after the date of expiry printed on the package.

### Please note:

Component 1 of the kit can be stored at room temperature.

Component 2 of the kit must be stored frozen at maximum -20°C immediately upon arrival.

If the MutaCLEAN® Rapid rapid Kit components 1 and 2 are completely mixed into a ready-to-use lysis reagent, the shelf life of this working solution in the refrigerator is one month from the date of mixing.

If a certain number of reactions are to be prepared for the rapid lysis procedure, Component 2 must be refrozen after use. For frequent use, Component 2 can also be aliquoted. This prolongs the shelf life of Component 2. When storing Component 2 in the refrigerator, it is recommended to use up the reagent within one month.

Table 2: Storage and Stability of the MutaCLEAN® Rapid lysis reagent.

Label	Storage and Stability	
NR1 Component 1		Store at +18°C to +35°C. Stable through date of expiry printed on kit label.
NR2 Component 2	Before use, reagent must be thawed completely	Store at ≤ -20°C. Stable through date of expiry printed on kit label.

## 6 GENERAL NOTES ON THE TEST AND TEST PROCEDURE

- The MutaCLEAN® Rapid Kit must be utilised by qualified personnel only.
- Good Laboratory Practice (GLP) has to be applied.

- Clinical samples must always be regarded as potentially infectious and all equipment used has to be treated as potentially contaminated.
- Component 1 contains guanidine hydrochloride which is an irritant. Always wear gloves and follow standard safety precautions.
- Component 2 contains biological material of animal origin. The ingredients are non-irritant.
- Do not let these buffers touch your skin, eyes, or mucous membranes. If contact does occur, wash the affected area immediately with large amounts of water; otherwise, the reagent may cause burns. If you spill the reagent, dilute the spill with water before wiping it up.
- Always wear gloves and follow standard safety precautions when handling these buffers.
- Do not pool reagents from different lots or from different bottles of the same lot. Immediately after usage, close all bottles in order to avoid leakage, varying buffer-concentrations or buffer conditions. After first opening, store all bottles in an upright position.
- Do not use the kit after its expiration date.
- Serious incidents are to be reported to Immundiagnostik AG and the national regulatory authorities.
- This product has been produced and placed on the market in accordance with the regulation (EU) 2017/746 (IVDR).

## 6.1 Waste Handling

- Dispose of unused reagents and waste should occur in accordance with country, federal state and local regulations.
- Material Safety Data Sheets (MSDS) are available from our scientists on [info@immundiagnostik.com](mailto:info@immundiagnostik.com), upon request.

## 7 PREPARATION OF THE WORKING SOLUTION

Prepare the MutaCLEAN® Rapid lysis reagent in a separate sterile tube before starting. The two components of the MutaCLEAN® Rapid Kit must be mixed in a ratio of 1:10.

Add 30 µL of Component 2 (NR2) to 270 µL of Component 1 (NR1). Prepare at least one sample (N) more than required to compensate for pipetting inaccuracy.

Table 3: Preparation of the MutaCLEAN® Rapid lysis reagent.

Volume needed per sample	Working solution
270 µl Component 1 (NR1)	270 µl x (N + 1)
30 µl Component 2 (NR2)	30 µl x (N + 1)

In addition to the samples always run a 'water control' in your lysis. Treat this water control analogous to a sample. A clean water control in your PCR results excludes contamination of the working solution.

## 8 SAMPLE MATERIAL

Lysis from sample material, such as the following:

- Sample type: dry pharyngeal swab samples
- Sample storage: Fresh or stored at +2°C to +8°C for up to 24 hours.

Perform sample preparation within 24 hours to avoid a negative impact on sample quality.

### 8.1 Protocol for manual use

This protocol is for manual use and serves as a guideline for adapting the kit to automated instruments.

#### Step 1

Add **300 µl MutaCLEAN® Rapid lysis reagent** (working solution) per tube containing the dry pharyngeal swab.

#### Step 2

Vortex the tube for 5 seconds.

#### Step 3

Incubate the sample for 10 minutes at room temperature

**(Note:** No mixing is required;

Do not exceed a maximum incubation time of 120 minutes.)

#### Step 4

Homogenize the lysate by shaking (optional mix by pipetting up and down or vortexing the tube).

#### Step 5

The lysate containing released RNA / DNA can be added direct in the PCR.

## 9 TROUBLESHOOTING

The following troubleshooting guide is included to help you with possible problems that may arise when isolating nucleic acids. For further questions concerning nucleic acid extraction, please do not hesitate to contact our scientists on [info@immundiagnostik.com](mailto:info@immundiagnostik.com).

### **Contamination during preparation of working solution**

Be sure that the MutaCLEAN® Rapid lysis reagent does not contact contaminated material during the preparation of the working solution or work. If necessary, the lysis reagent must be rejected and prepared again.

For each sample, take a fresh tip to add the MutaCLEAN® Rapid lysis reagent to the swab collection tube and make sure that the tip has not come into contact with the tube of the sample material.

Run a water control as a sample to verify the purity of the working solution.

### **Incubation time exceeded**

Incubate the sample in the MutaCLEAN® Rapid lysis reagent for 10 minutes.

Exceeding the incubation time of more than 120 minutes leads to false results in the following PCR due to unstable lysates.

### **Incubation time undershot**

Incubate the sample in the MutaCLEAN® Rapid lysis reagent for 10 minutes.

Falling below the incubation time of 10 minutes leads to a low nucleic acid yield and causes false results in the following PCR.

### **Incorrect storage of kit components**

Component 2 must be frozen at  $\leq -20^{\circ}\text{C}$  upon arrival and after preparing the working solution. If the component is stored at  $> -20^{\circ}\text{C}$ , inhibition may occur in the PCR.

Store Component 1 at  $+18^{\circ}\text{C}$  to  $+35^{\circ}\text{C}$  upon arrival.

### **Absence of Component 2**

Add Component 2 to Component 1 in a 1:10 ratio as prescribed to prepare the MutaCLEAN® Rapid lysis reagent as a working solution before use.

If Component 1 has been added to the sample material, Component 2 can be added subsequently and quickly.

If an incubation period has already taken place and Component 2 has been forgotten in the working solution, this may lead to inhibition of the PCR. Please request a new dry pharyngeal swab.

### Use of incorrect volume

Resuspend the dry swab samples with 300 µL MutaCLEAN® Rapid lysis reagent as instructed.

A deviating volume of more or less than 15 % of the recommended volume may lead to incorrect results in the following PCR.

### Precipitates of guanidine hydrochloride in Component 1

Component 1 is a clear solution and should not be used when precipitates have formed. Warm up the solutions at +18°C to +35°C or in a 37°C water bath until the precipitates have dissolved.

## 10 ABBREVIATIONS AND SYMBOLS

DNA	Deoxyribonucleic Acid		Manufacturer
RNA	Ribonucleid acid		Catalog number
PCR	Polymerase chain reaction		Batch code
	Component 1 (NR1)		Content
	Component 2 (NR2)		Use by YYYY-MM-DD
	Storage temperature		Consult instructions for use
	Storage temperature		European Conformity
	Contains sufficient for <n> test		<i>In vitro</i> diagnostic medical device
	Contains biological material of animal origin		Unique Device Identification

The product has been classified and marked in accordance with EU Directives/  
Ordinance on Hazardous Materials



Acute toxicity, Category 4, H302

Acute toxicity, Category 4; H332

Skin irritation, Category 2; H315

Eye irritation, Category. 2; H319







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